



# Economic Cost-Effectiveness of the Implementation of the Quality Standard ISO 9001 in the Health Sector

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The quality standard ISO 9001 helps and enables organizations, regardless of the sector where they exist, to implement the quality management properly. Recent years have attracted attention to the possibilities of implementing this standard in the health sector and the economic viability of that long-term investment. Health care organizations are recognizing the value system that combines all the criteria for managing quality, including management of business, compliance and management of procedural steps, and most importantly, the total quality management. In general, the implementation of ISO 9001:2008 standard for quality in health care institutions is seen as an opportunity to improve the quality of health care, and the entire process is to be completed by reducing costs and improving services in the sector. The implementation of a quality standard is directed towards patients, medical staff, and management in order to achieve reduction and complete relief from the pain, correct and professional services, conducted services with an appropriate skilled and professional care to obtain results that are comparable to known standards, and protection services with appropriate insurance policies, and the management expects the implementation of a quality system to justify and return their investments. The methods used in this paper are based on the quality standard ISO 9001:2008—Quality Management System and the Guidelines for Improving Performance, developed based on ISO 9004:2000: Quality Management System—Guidelines for Continuous Improvement. These guidelines contain a big part of the text in ISO 9004:2000, but they are supplemented with specific guidelines for their implementation in the health sector. The implementation of the system and monitoring guidelines evidently contributes to the overall resolution and closure of problems in over 50% of cases. This not only results in saving money for the institution, but it also globally leads to reduced variations in the healing process. Expected benefits from implementing the system in the health care sector in the Republic of Macedonia relate to providing a substantial foundation for obtaining all the necessary facilities and reduction of the costs by reducing the inappropriate staff in exactly determined departments. Implementation of future accreditation processes can be accomplished in a much shorter period of time, especially when there is good communication and cooperation among the departments. Improved working systems, processes, and final results inevitably contribute to happy and healthy patients.

*Keywords:* ISO 9001, ISO 9004:2000, guidelines for improvement

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## Introduction

The International Organization for Standardization (ISO) promotes the use of ISO 9000 series of quality management systems ranging from two basic points. First, it is an internationally accepted system, and secondly, it embodies all the world standards. Wealth of knowledge and experience in quality improvement in the health sector has accumulated globally over many decades. Despite this wealth of experience, the problem often faced by policymakers at the national level in developing countries and in high developed countries is to know which strategy will have the greatest impact on quality results provided in their health systems. It seems that a quality strategy that is in accordance with the European standards and integrated into existing strategic initiatives gives the best results (ISO Central Secretariat, 2009).

This research aims to focus on the quality of health care systems and to provide adequate explanations why the quality systems need to be implemented in the health sector, what are its benefits and disadvantages, and also to point out the real situation, which is present on the territory of the Republic of Macedonia. There are two main arguments in favour of the fact that it is crucial to promote and focus on quality in health care systems. Even where health systems are well developed and have open and available resources, there is clear evidence that quality remains a serious problem, and without the introduction of a system, the expected results cannot be achieved. In the health systems, especially in developing countries, the utilization of resources should be optimized and the coverage of the population should be expanded, and the process of continuous improvement should be based on the exact determined strategy with continuous monitoring of the World Health Organization guidelines and the guidelines of the International Accreditation Agency. However, the best results are undeniably achieved with the new investments in the health system (ISO, 2014).

There are two main arguments for promoting a focus on quality in health systems at this time. Even where health systems are well developed and resourced, there is clear evidence that quality remains a serious concern, with expected outcomes not predictably achieved and with wide variations in standards of health care delivery within and between health care systems (World Health Organization, 2007). Where health systems, particularly in developing countries, need to optimize resource use and expand population coverage, the process of improvement and scaling up needs to be based on sound local strategies for quality so that the best possible results are achieved from new investments (World Health Organization, 2006).

The universally recognizable ISO 9001:2008 standard is in use in the health systems in numerous high, medium developed, and developing countries. It represents a universal platform that supports and coordinates the enormous number of elements and processes in the health sector. It provides promotion and strengthening of the existing health sector and provides coordination with any other area. Monitoring of the standard implementation and establishment of the quality policy promote a foundation for the sustainable, healthy, and reliable health sector or a basis for setting up and connecting to all set requirements that are in accordance with the World Health Organization, the International Agency for Standardization, or Joint Commission on Accreditation of Healthcare Organizations (JCAHO)—agency standardization of the healthcare organizations of the continental United States (US). All other certification and accreditation processes simplify their implementation and thus reduce their costs. The implementation facilitates and enhances the understanding and the division of roles and responsibilities. It improves the communication/coordination among separate segments. It increases accountability by requiring measurable improvement goals. It results in improved operating systems, processes, and results.

All system defects are easily recognizable and processed. It enables the development of a very well organized health institution with prevalent and controlled processes, and all that is accompanied by supporting documentation. It ensures safety and effectiveness of the documented processes. It focuses on patient care, satisfaction, and his/her safety. It reduces the errors associated with external influences. Documentation and records in every part of the institution are being improved. This results in patients' boost of confidence and also improves the relationship with the entire community. What must also be understood is that the external customers are served by the internal customers (employees). There is, therefore, a need to focus on the requirements and expectations of both internal and external customers (Pekar, 1995).

Quality system requires establishing a quality manual, which creates a documented quality management system which determines the organizational structure, procedures, and processes and defines the quality objectives. It provides and approves guidelines to ensure proper care for patients and specifically defines the helping processes. Actual documents must be available and indexed. There must be a documented control process. It provides leadership, structure, and resources and proves the quality politics of the entire health system.

If the quality management system is consistently implemented, the institution has a far greater insight into the expertise of the employee staff and whether control procedures and guidelines are implemented correctly. Each health institution is required to have certified and hired internal auditors who are properly certified with full-time jobs (Roger, 2006).

This quality system and continuous improvement suggest the use of guidelines for continuous improvement. Guidelines for continuous quality improvement in the health sector are published by ISO on September 20, 2001, in the first "International Workshop Agreement (IWA)" (World Health Organization, 2003). Guidelines for continuous improvement are made based on ISO 9004:2000: Quality Management System—Guidelines for Continuous Improvement. These guidelines contain a large part of the text of ISO 9004:2000, but they are fulfilled with specific guidelines for their implementation in the health sector. The document provides a framework for designing and improving processes which are based on the quality system in a health institution. What is important is to constantly follow the rules and regulations set by these guidelines, which will be constantly rated and as such will be used in workflows. For all of these directions given by the guidelines, the organization determines whether to follow or not, but is primarily intended for institutions that are in the process of accreditation or certification (ISO, 2005).

Many organizations' quality managers have to learn new quality management techniques while simultaneously building the information infrastructure needed to do the work. In many organizations, the technology of quality management is relatively new and has only been lightly used and tested by the staff (Varkey, 2010).

As a huge sector, the automotive sector works and cooperates with thousands of promoters of health care and spends significant resources in the health care programme. The purpose of these guidelines is to achieve a systematic implementation of the improvement process in order to achieve continuous improvement, prevention of errors, and other unwanted results in a reduction of the variations and organizational errors, "organizational waste" which generally represents additional activities without real value. Major improvements included in the new revised version of the manuals for continuous improvement include the following:

(1) "Translation" of the quality terminology: Terms related with the language and conditions that will be easily understandable for the health professionals;

(2) Adding of quite a number of requirements of the paragraphs of the ISO 9004:2000 system related with attitudes and advice such as “what to look for” and “manual/examples”.

Generalized implementation of ISO 9000 quality management system by health facilities is seen as a means of rationalizing the relationship among patient-health workers and represents an opportunity to improve the quality of the health care, and as a result, an appropriate cost reduction follows.

### **Objectives**

This paper is based on the world literature research in order to determine the significance and prospects of the implementation of quality standards in the health sector. Opportunities to apply these proven theories in Macedonian health sector already exist, and field trials that are underway will even give a clearer picture of how this is done. The objectives of the research are to examine the possibilities of implementing the standard in both public and private institutions, to determine the level of knowledge of the standard by health care professionals, and to prove the feasibility of the implementation of standards in institutions that have already been implemented and properly enforced.

Implementation of a quality standard is actually directed towards patients and medical staff and management should strive to achieve complete relief of pain, correct and professional services, services to be implemented with an adequate, skilled, and professional care to achieve comparable results, and services that will be protected by appropriate insurance policies. Despite all of these, of course one expects the implementation of the quality management system to justify the return on investment. One of the objectives was to assess the current state of public and private institutions in Macedonia individually and perhaps more importantly, to assess how to achieve better results at the level of overall health sector in light of the use of the benefits of a comprehensive implementation of the quality system in the Republic of Macedonia.

### **Materials and Methods**

This study will include public health and private health institutions of secondary and health territory of the Republic of Macedonia. For this purpose, questionnaires will be developed and they should be filled in by health managers or in accordance with the requirements of the standard. What you first need to determine is whether the institution has implemented the standard for quality, and then to approach into filling in the appropriate questionnaire. If the health institution has implemented quality standards, it will continue filling in the other questionnaires related to the guidelines for continuous improvement.

Methods that are used in this paper are based on the quality standard ISO 9001:2008, Quality Management System and the Guidelines for Improving Performance, developed based on ISO 9004:2000: Quality Management System—Guidelines for Continuous Improvement. These guidelines contain a large part of the text of ISO 9004:2000, but they are supplemented with specific guidelines for their implementation in the health sector. In the form of typical questions, this approach provides an opportunity for the management organization to evaluate its effectiveness for each of the main clauses according to ISO 9004.

### **Results**

According to the world literature, it is determined that it is most useful for the health institutions to implement the quality standard ISO 9001:2008: Quality Management System and the Guidelines for Improving Performance, developed based on ISO 9004:2000, as well as the guidelines for continuous improvement.

Therefore, the use of a comprehensive questionnaire may allow assessing the maturity of the quality management system in each institution with respect to each clause according to ISO 9004 on a scale ranging from 1 (no formal system) to 5 (best-in-class performance).

The results obtained can be used for reviewing the achievements of the health care institution when it can be assessed whether the institution progresses or regresses in terms of implementation of the standard. The results suggest that this approach and the principle of operation is not a substitute for an internal review and that it can be used to upgrade the quality system.

### Conclusion

This paper is trying to prove the feasibility of implementation of the quality system, better organization that it provides, as well as simplification of procedures and work procedures in order to improve services and the health of patients. Worldwide experiences already speak about it through a series of examples developed in medical journals and medical databases. Expected benefits from implementing the system in the health care sector in the Republic of Macedonia relate to providing a substantial foundation for providing all the necessary facilities and reduction of the costs by reducing the inappropriate staff in exactly determined departments. Implementation of future accreditation processes can be accomplished in a much shorter period of time, especially when there is good communication and cooperation among the departments. Enhanced system for work processes and the final results inevitably contribute to happy and healthy patients. Financial savings that are evident in health care institutions have introduced and implemented the quality system according to ISO 9001:2008 and they allow diverting these resources for the development and adoption of new treatment technologies that will inevitably lead to better health for all, which also represents the health policy objective of each country.

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